

**Small Business Economic Impact Statement
for Rule Concerning Automated Drug Distribution Devices
WAC 246-872**

1. Briefly describe the proposed rule.

Hospitals and other healthcare facilities have purchased automated drug distribution devices to store and distribute medications in a secure manner outside a pharmacy and to improve access to medications for administration to a patient. The devices also ensure that each patient is charged appropriately and provides accountability for each unit of medication.

The proposed rule will create a new chapter in WAC 246 and will adopt uniform standards for the use of automated drug distribution devices for those facilities that choose to use them. In addition, the proposed rules will include current Board of Pharmacy requirements for drug storage, security, and accountability. It will recognize the automated drug distribution as an appropriate storage site for controlled substances.

The current rule applies to mechanical devices that are no longer available. For the few devices in use, the mechanical device rule will remain in place.

2. Is a Small Business Economic Impact Statement (SBEIS) required for this rule?

Yes, the costs of compliance by hospitals and other health care facilities exceed minor costs on small businesses. The automated devices are purchased voluntarily by hospitals and other healthcare facilities. However, the proposed rule ensures that the Board of Pharmacy requirements for drug storage are met by generating reports that the pharmacist must review. The cost of generating the required reports is an additional cost, if a provider decides to purchase automated drug distribution devices. The additional cost exceeds minor costs.

The costs to comply with the mechanical devices are greater than for automated drug distribution devices, since they no longer record medications removed and require a separate paper record system to meet Board of Pharmacy requirements.

3. Which industries are affected by this rule?

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8051 Skilled Nursing Care				
8062 General Medical & Surgical Hospital				
			Average Employment	
	Number of Firms	Total Employment	Small Business	Large Business
8051 Skilled nursing care facilities	281	26,407	14.7	144.2
8062 General medical & surgical hospital	146	78,593	11.1	2027.7

4. What are the costs of complying with this rule for small businesses (those with 50 or fewer employees) and for the largest 10% of businesses affected?

It was estimated that costs of generating reports for small facilities would be \$600.00 per year. The estimated cost for large facilities is \$9,600.00 per year. The higher cost for large facilities is due to the difference in the number of automated devices used by small and large businesses.

5. Does the rule impose a disproportionate impact on small businesses?

Yes, when the costs for small and large facilities are averaged, there is a disproportionate impact on small businesses.

	Avg. Employment	Avg. Employment	Compliance Costs	Compliance Costs	Avg. Costs	Avg. Costs
	Small Business	Large Business	Small Business	Large Business	Small Business	Large Business
8051 Skilled nursing care facilities	14.7	144.2	\$600	\$9,600	\$40.82	\$66.57
8062 General medical & surgical hospital	11.1	2027.7	\$600	\$9,600	\$54.05	\$4.73

As the table indicates, only SIC 8062 employers would be disproportionately affected by the costs of the proposed rule. Average per employee costs for small businesses in this industry \$54.04 is much higher than \$4.73 which is the average per employee costs of compliance for large businesses.

6. If the rule imposes a disproportionate impact on small businesses, what efforts were taken to reduce that impact (or why is it not "legal and feasible" to do so) by

a) reducing, modifying, or eliminating substantive regulatory requirements?

The Board of Pharmacy standards for drug storage apply to all facilities and incorporate several Federal standards. No exemptions are allowed.

b) simplifying, reducing, or eliminating record keeping and reporting requirements?

The proposed rule language allows the facility flexibility in how they comply with drug storage standards.

c) reducing the frequency of inspections?

[Answer here]

d) delaying compliance timetables?

[Answer here]

e) reducing or modifying fine schedules for noncompliance?

Fines are not levied against firms for noncompliance of standards for drug storage.

f) any other mitigation techniques?

Pharmacist investigator would provide technical assistance to the facility to simplify record keeping and reporting requirements.

7. How are small businesses involved in the development of this rule?

Stakeholders included employees from small as well as large healthcare facilities. Representatives from small facilities attended the stakeholders meeting, reviewed and commented on the proposed rule, sent e-mails, and made phone calls to express concerns. A listserv notice was used to confirm the proposed rule language.